



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,926	05/24/2001	Kok-Hwee Ng	F-5727 (1417P P 590)	1675

7590 03/03/2006

Bradford R.L. Price, Esq.  
Senior Counsel  
Baxter International Inc.  
Route 120 and Wilson Road, RPL-30  
Round Lake, IL 60073

EXAMINER

TOMASZEWSKI, MICHAEL

ART UNIT PAPER NUMBER

3626

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/864,926	NG ET AL.	
	Examiner	Art Unit	
	Mike Tomaszewski	3626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Notice To Applicant***

1. This communication is in response to the application filed on 01 November 2005. Claims 39-47 have been amended and remain pending. Claims 1-38 have been canceled.

### ***Specification***

2. The amendment filed 01 November 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The newly added recitation of "determining that a blood component collection kit is compatible with the selected blood component collection application" within claims 39, 43, 45 and 47; and "determining if an operator of the blood component collection instrument is qualified for the selected blood component collection application" within claims 41 and 44 appears to be new matter. In particular, Applicant does not point to, nor was the Examiner able to find, any support for these newly added recitations within

Art Unit: 3626

the specification as originally filed. As such, Applicant is respectfully requested to clarify the above issues and to specifically point out support for the newly added limitations in the originally filed specification and claims.

Applicant is required to cancel the new matter in the reply to this Office Action.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The specification is objected to under 35 U.S.C. § 112, first paragraph, because the specification, as originally filed, does not provide support for the invention as is now claimed for the reasons given in section 2 above.

***Claim Rejections - 35 USC § 112***

5. Claims 39, 41, 43, 44, 45 and 47 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

Art Unit: 3626

inventor(s), at the time the application was filed, had possession of the claimed invention and for the reasons set forth in the objection to the specification above.

Independent claims 39, 43, 45 and 47 recite limitations that are new matter, as discussed above.

Claims 41 and 44 also recite limitations that are new matter, as discussed above. Moreover, claims 41 and 44 incorporate the deficiencies of independent claims 39 and 43, through dependency, and are therefore, rejected accordingly.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**NOTE:** The following rejections assume that the subject matter added in the amendment filed on 07 October 2005 is not new matter and are provided hereinbelow for Applicant's consideration on the condition that Applicant properly traverses the new matter objections and rejections set forth in sections 2-5, supra, in the next communication sent in response to the present Office Action.

7. Claims 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fletcher-Haynes et al. (US 2001/0034614; hereinafter Fletcher-Haynes).

(A) Claims 39 and 43 have been amended, in pertinent part, to recite the step of “determining that a blood component collection kit is compatible with the selected blood component collection application.”

Fletcher-Haynes, however, discloses the step of determining that a blood component collection kit is compatible with the selected blood component collection application (Fletcher-Haynes: par. [0015], [0062] and [0137]).

Moreover, although Fletcher-Haynes does not expressly disclose the specific term “nomogram,” the use of graphic representations of numerical relations (i.e., nomograms) is well known and obvious, as evidenced by Fletcher-Haynes. In particular, Fletcher-Haynes teaches the use of graphic representations of numerical relations to determine optimal blood processing performance (Fletcher-Haynes: par. [0307]; Fig. 10; Examiner considers Fig. 10 to be one example of a nomogram.).

The remaining features of claims 39 and 43 are rejected for the reasons set forth in the previous Office Action and incorporated herein.

(B) Claims 41 and 44 have been amended, in pertinent part, to recite the step of “determining if an operator of the blood component collection instrument is qualified for the selected blood component collection application.”

Art Unit: 3626

Fletcher-Haynes, however, discloses the step of determining if an operator of the blood component collection instrument is qualified for the selected blood component collection application (Fletcher-Haynes: par. [0074], [0079], [0114], [0120] and [0132]).

The remaining features of claims 41 and 44 are rejected for the reasons set forth in the previous Office Action and incorporated herein.

(C) Claims 40, 42 and 46 have not been amended and are rejected for the same reasons given in the previous Office Action.

(D) Claim 45 has been amended, in pertinent part, to recite "said system determining that a blood component collection kit is compatible with the selected blood component application."

Fletcher-Haynes, however, discloses said system determining that a blood component collection kit is compatible with the selected blood component collection application (Fletcher-Haynes: par. [0015], [0062] and [0137]).

Moreover, although Fletcher-Haynes does not expressly disclose the specific term "nomogram," the use of graphic representations of numerical relations (i.e., nomograms) is well known and obvious, as evidenced by Fletcher-Haynes. In particular, Fletcher-Haynes teaches the use of graphic representations of numerical relations to determine optimal blood processing performance (Fletcher-Haynes: par. [0307]; Fig. 10; Examiner considers Fig. 10 to be one example of a nomogram.).

Art Unit: 3626

The remaining features of claim 45 are rejected for the reasons set forth in the previous Office Action and incorporated herein.

(E) Claim 47 has been amended, in pertinent part, to recite “a fourth segment for determining that a blood component collection kit is compatible with the selected blood component application.”

Fletcher-Haynes, however, discloses a fourth segment for determining that a blood component collection kit is compatible with the selected blood component collection application (Fletcher-Haynes: par. [0015], [0062] and [0137]).

Moreover, although Fletcher-Haynes does not expressly disclose the specific term “nomogram,” the use of graphic representations of numerical relations (i.e., nomograms) is well known and obvious, as evidenced by Fletcher-Haynes. In particular, Fletcher-Haynes teaches the use of graphic representations of numerical relations to determine optimal blood processing performance (Fletcher-Haynes: par. [0307]; Fig. 10; Examiner considers Fig. 10 to be one example of a nomogram.).

The remaining features of claim 47 are rejected for the reasons set forth in the previous Office Action and incorporated herein.



***Response to Arguments***

8. Applicant's arguments filed 01 November 2005 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 01 November 2005.

(A) At page 9 of the 01 November 2005 response, Applicant argues the selection of the blood component to be collected under the Fletcher-Haynes procedure is therefore not necessarily in accordance with any nomogram, as in the present invention, but is, instead, subject to external considerations of current inventories.

In response, Examiner respectfully submits that Applicant is not the first to have invented the nomogram, per se, and that once the prior art establishes that the selection of blood components to be selected is based on optimization or manipulation of data (Fletcher-Haynes: par. [0062]), the skilled artisan would have readily recognized that a nomogram is nothing more than a graphical manipulation of data.

(B) At page 10 of the 01 November 2005 response, Applicant argues Fletcher-Haynes does not fairly disclose or teach methods (Claims 39-44), systems (Claims 45-46) or media (Claim 47) that, *inter alia*, determines whether blood component collection kit is compatible with a select blood component collection application.

In response, Examiner respectfully submits that Fletcher-Haynes does indeed teach the methods, systems and media that, *inter alia*, determine whether blood

Art Unit: 3626

component collection kit is compatible with a select blood component collection application. For example, Fletcher-Haynes teaches operators determining what tubing set (i.e., blood collection kit) is required (i.e., compatible) for the donation (i.e., blood component collection application) (Fletcher-Haynes: par. [0015]). Another Fletcher-Haynes example further teaches that different donation procedures (i.e., blood component collection applications) require specific corresponding (i.e., compatible) tubing sets (i.e., blood collection kits) (Fletcher-Haynes: par. [0062]).

(C) At page 10 of the 01 November 2005 response, Applicant argues there does not appear to be any determination whether the operator of the blood component collection instrument is qualified to run the selected blood component collection application or process, as recited in amended Claims 41 and 44.

In response, Examiner respectfully submits that Fletcher-Haynes does indeed teach determining whether the operator of the blood component collection instrument is qualified to run the selected blood component collection application or process. For example, Fletcher-Haynes teaches that operators, depending on their technical skills and/or qualifications, may or may not be qualified to run different collection procedures (i.e., selected blood component collection application or process) (Fletcher-Haynes: par. [0120]). Fletcher-Haynes further teaches that operators are assigned varying levels of security clearance and system access depending on, *inter alia*, the operator's role, skills, and qualifications (par. [0074], [0079], [0114], [0120] and [0132]). Hence, at the

Art Unit: 3626

time of system access authorization or login, a determination is made as to what procedures the operator is qualified to access (i.e., run).

(D) At page 10 of the 01 November 2005 response, Applicant argues that Applicants are not in agreement with the reasons cited in many of the rejections of the dependent claims.

In response, Examiner respectfully submits that, insofar as no specific arguments regarding features of dependent claims are proffered, there does not appear to be any distinctive difference between the claimed limitations and the specific portions of the prior art applied by the Examiner.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3626

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied art teaches extracorporeal blood processing methods and apparatus (5,795,317); a security badge for automated access control and secure data gathering (5,960,085); an extracorporeal blood processing information management system (US 2003/0154108); and extracorporeal blood processing methods and apparatus (6,234,989).

The cited but not applied prior art also includes non-patent literature articles by Hankins, Thomas L. ("Blood, dirt, and nomograms: A particular history of graphs" Mar 1999. Isis. Vol. 90, Iss. 1. pg. 50.) and Karjalainen, J. ("QT interval as a cardiac risk factor in a middle aged population" Jun 1997. Health & Medical Complete. Vol. 77, Iss. 6. pg. 543.).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

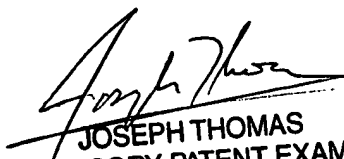
Art Unit: 3626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MT

~~NA~~

1.20.06

  
JOSEPH THOMAS  
SUPERVISORY PATENT EXAMINER